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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,183	05/14/2001	Kerry Bradley	SJ1-010US	9316
36802	7590	06/08/2004	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,183	BRADLEY ET AL.	
	Examiner	Art Unit	
	George R Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67 and 76-95 is/are pending in the application.
- 4a) Of the above claim(s) 78-84 and 92-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 67, 76, 77, 85-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 78-84 and 92-95 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper dated 3/19/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 67, 76, 85, and 87-91 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Salo et al (6278894).

Claims 67, 76, 85, and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Chirife (5154171). Chirife states in column 3 that his system is used for measuring ventricular ejection fraction for the right or “left” heart and shows in figure 3 an example of the system when used in the ventricle using four electrodes in the ventricular chamber, using an electrode can and tip electrode to supply the constant current, and using ventricular electrodes 18 and 20 to sense the voltage (column 6) to determine impedance to adjust the pulse generator (columns 6 and 7).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 77 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salo et al (or Chirife).

Salo (or Chirife) discloses the claimed invention except for the combination of the right ventricle electrode and housing electrode for the first pair of electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance measurement system as taught by Salo (or Chirife), with the combination of the right ventricle electrode and housing electrode for the first pair of electrodes since it was known in the art that impedance measurement systems use the combination of the right ventricle electrode and housing electrode for the first pair of electrodes to deliver the current to provide a current field

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across the heart to span some region of the left ventricle to easily determine and measure impedance.

In addition, Salo (or Chirife) discloses the claimed invention but does not disclose expressly the combination of the right ventricle electrode and housing electrode for the first pair of electrodes. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the impedance measurement system as taught by Salo (or Chirife) with the combination of the right ventricle electrode and housing electrode for the first pair of electrodes, because Applicant has not disclosed that the combination of the right ventricle electrode and housing electrode for the first pair of electrodes provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the first electrodes being two RV electrodes, two LV electrodes, or a RV and RA electrode (or two LV electrodes) as taught by Salo (or Chirife), because they provide a current field across the heart using existing implanted leads to span some region of the left ventricle to easily measure the impedance of the heart.

Therefore, it would have been an obvious matter of design choice to modify Salo (or Chirife) to obtain the invention as specified in the claim(s).

Claims 88-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chirife.

Chirife discloses the claimed invention except for the coronary sinus lead with LV tip and LV electrode for the second pair of electrodes and a RV lead with a pair of electrodes, including an RV ring electrode, for the first pair of electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the impedance

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measurement system as taught by Chirife, with the coronary sinus lead with LV tip and LV electrode for the second pair of electrodes and a RV lead with a pair of electrodes, including an RV ring electrode, for the first pair of electrodes since it was known in the art that impedance measurement systems use the coronary sinus lead with LV tip and LV electrode for the second pair of electrodes to measure the impedance of the left ventricle without inserting the catheter directly in the LV and risking thrombus formation and since it was known to use an RV lead with a pair of electrodes, including an RV ring electrode, for the first pair of electrodes to easily provide the current field across the heart with existing implanted leads to span some region of the left ventricle to measure and determine impedance.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. The argument that the Salo reference does not teach measurement of myocardial impedance "to determine wall dynamics" is not persuasive since the claims do not contain any limitation to determining wall dynamics. In addition, Salo measures impedance in the heart and therefore measures myocardial impedance and states that the sensing electrodes are sensitive to left ventricular volume and wall motion (column 2).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
June 2, 2004


GEORGE R. EVANISKO
PRIMARY EXAMINER

6/2/4